IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., REBIOTIX INC. Plaintiffs, v. FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., and FINCH THERAPEUTICS HOLDINGS, LLC. Defendants.	C.A. No. 21-1694-JLH Redacted Version of D.I. 295
FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., FINCH THERAPEUTICS HOLDINGS, LLC, and REGENTS OF THE UNIVERSITY OF MINNESOTA Counterclaim-Plaintiffs/Reply Defendants, v. FERRING PHARMACEUTICALS INC., and REBIOTIX, INC. Counterclaim-Defendants/Reply Plaintiffs.	

FERRING'S BRIEF IN REPLY TO FINCH/UMN'S BRIEF IN OPPOSITION TO FERRING'S MOTIONS FOR SUMMARY JUDGMENT AND DAUBERT MOTION

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I. INTRODUCTION

Finch/UMN has failed to mount an effective defense to Ferring/Rebiotix's motions for summary judgment and *Daubert* motion. As set forth below, the motions should be granted.

II. ARGUMENT

A. Partial summary judgment of no copying is appropriate, as is summary judgment of no willful infringement

Finch/UMN's arguments concerning copying as a secondary consideration and allegations of willful infringement are based on the same core factual allegations. For the UMN patents, Finch/UMN's evidence, even if credited, shows only access to—not use of—any confidential information in developing the accused product. For the Borody patents, Finch/UMN fails even to show access to any confidential information with any nexus to the claims. Instead, this evidence is a tangential narrative solely intended to vilify Ferring/Rebiotix. As such, allowing this evidence to remain in the case runs a significant risk of prejudice under Rule 403.

First, despite listing UMN material Ms. Jones allegedly had access to, D.I. 281 at 1-2, unlike in *Liqwd, Inc. v. L'Oreal USA, Inc.*, Finch/UMN do not point to any evidence that Ferring **used** those materials to develop REBYOTA. 941 F.3d 1133, 1139 (Fed. Cir. 2019). Moreover, Finch/UMN's assertion that Dr. Benson confirmed the "obvious nexus" to the UMN claims, D.I. 281 at 2, is incorrect. The cited passages from Dr. Benson's responsive expert report fail to establish (1) that what was allegedly copied was the claimed invention, *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 999-1000 (Fed. Cir. 1986), and (2) that the material that was allegedly copied had a nexus to the patent claims, *Apple Inc. v. Samsung Elecs. Co.*, 816 F.3d 788, 798 (Fed. Cir. 2016); *see also Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010). Indeed, it is undisputed that the process described in the UMN patents' Examples is not the process used to make REBYOTA. D.I. 260, Ex. 11 at 162:18-164:2. Regardless, it is not

sufficient to show copying of features in the Examples in the UMN patents if those features are not present in the claims. *Dako Denmark A/S v. Leica Biosys. Melbourne Pty Ltd*., 662 F. App'x 990, 997-98 (Fed. Cir. 2016); *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011).

Finch/UMN argue that "Dr. Benson confirmed all claim elements (described in the copied materials) are present in REBYOTA, which was developed ***after*** Ms. Jones gained access to UMN's patented protocol, and ***while*** she was circulating it internally to REBYOTA developers." D.I. 281 at 3 (emphasis in original). But Dr. Benson's responsive report only provides the same narrative found in Finch/UMN's brief. *Compare* D.I. 281 at 1-4 *with* D.I. 283, Ex. 64 at ¶¶1374-79. These allegations show only that Lee Jones had **access** to confidential information, but do not include **evidence** that it was used to make REBYOTA. Finch/UMN further argue that Lee Jones's preparation of an internal business plan and subsequent revisions to it are somehow relevant. But neither the revised business plan nor Ms. Jones's testimony supports an inference of copying **the claimed invention**. The documents show, at most, that the idea of FMT came from UMN, that FMT was in the prior art, and that FMT itself is not patentable. Finch/UMN simply fails to connect the dots to provide a viable claim of copying.

With respect to the Borody patents, there is no evidence that anything relevant was copied. Lee Jones simply testified that she had heard of Dr. Borody at some point, not that she had seen any specific patent applications or other documents, let alone documents relevant to the claims of the Borody patents. The only specific document to which Finch/UMN point is an email dated **after** the REBYOTA formulation was finalized. D.I. 282, Ex. 76.

With respect to Finch/UMN's allegations of copying as the basis for its allegations of willful infringement, for two of the Borody patents—the '193 patent and the '080 patent—that evidence is of no moment because the patents were filed and issued after the litigation was filed,

so they cannot form the basis of Finch/UMN's willfulness claim. *WBIP, LLC v. Kohler Co*., 829 F.3d 1317, 1341 (Fed. Cir. 2016).

With respect to the UMN patents, because the conduct Finch cites occurred prior to the patent issuance, it must constitute "particularly egregious behavior." *Bioverativ Inc. v. CSL Behring LLC*, No. 17-914-RGA, 2020 WL 1332921, at *2-*4 (D. Del. Mar. 23, 2020). In an effort to avoid the application of this heightened standard, and even as it points primarily to Lee Jones's alleged access to the patent application and contemporaneous materials, Finch/UMN asserts in a footnote that "the evidence does not solely 'predate the issuance' of the patents," citing only "*id.*" D.I. 281 at 6 n.5. Finch/UMN cites no actual record evidence and it is unclear what—if anything—this "*id*." refers to. This falls far short of the "particularly egregious conduct" required by *Sonos, Inc. v. D&M Holdings Inc.*, No. 14-1330-WCB, 2017 WL 5633204, at *4 (D. Del., Nov. 21, 2017) and *Bioverativ*, 2020 WL 1332921, at *2-*4.

B. The Markush group in the asserted claims of the UMN patents is improper

In January 2018, the MPEP was revised to provide more detailed guidance on what is, and is not, a proper Markush group. Although there was some discussion of Markush groups in earlier versions of the MPEP, *see* MPEP § 2173.05(h) (9th Ed., Rev. 07.2015 (Nov. 2015)), new Markush-group-specific sections were added in January 2018. *See* MPEP §§ 2117, 706.03(y) (9th Ed., Rev. 08.2017 (Jan. 2018)). The new guidance states, "A Markush grouping is proper if the members of a group share a single structural similarity **and** a common use." MPEP § 2117 (emphasis added). As stated in a companion section to Section 2117, also added in 2018, a Markush grouping is improper "if either: (1) the members of the Markush group do not share a 'single structural similarity' or (2) the members do not share a common use." MPEP § 706.03(y). This requirement can be satisfied: (a) if they are members of the same class and are known in the art to be functionally equivalent, or (b) if there is a substantial structural feature in common and

the common use flows from that substantial structural feature. *Id.*

Finch/UMN cite *Lexington Luminance LLC v. Amazon.com Inc.*, 601 F. App'x 963, 968 (Fed. Cir. 2015), supposedly for the proposition that only the PTO, and not courts, can determine indefiniteness due to improper Markush group claiming. D.I. 281 at 6. But *Lexington* was decided prior to the most recent MPEP revisions and was narrowly focused on whether the Markush claim improperly used the open "comprising" rather than the closed "consisting of." Similarly, in *Microsource, LLC v. Eco World Grp., LLC*, 587 F. Supp. 3d 770, 831 (N.D. Iowa 2022) the sole issue decided was whether the claim at issue was an improper "comprising" claim.

While the MPEP does not have the force of law, it is "entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith." *Molins PLC v. Textron Inc.*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995). Finch/UMN mis-cite *Niazi Licensing Corp. v. St. Jude Medical S.C., Inc.*, which did not hold that it was "highly relevant" that the examiner added Markush group language, but rather noted that "it is highly relevant that the examiner understood th[e] phrase ["visually negligible"] throughout prosecution . . . ." 30 F. 4th 1339, 1348 (Fed. Cir. 2022). Here the prosecution history and specifically the interview summary, indicates the change was applicant-initiated, not examiner-initiated. Ex. A at FINCH_UMN_0007981. Similarly, *Guangdong Alison Hi-Tech Co. v. International Trade Commission*, 936 F.3d 1353, 1361-62 (Fed. Cir. 2019) is inapplicable here. As discussed *infra* § II.G, the term "lofty batting" was not indefinite because it was supported by many statements and descriptions in the specification, including references to specific brand-name products and detailed discussion of a number of characteristics. It did not involve Markush claims at all.

Finch/UMN next argue that the enumerated classes of bacteria are structurally similar because they belong to the same art-recognized class. D.I. 281 at 8. However, Finch/UMN do not

identify what that class is, nor do they provide any evidentiary support for this assertion. Then, rather than arguing that the group members are all "functional equivalents," as required under the MPEP, Finch/UMN argue that they "share a common use: 'reconstituting the normal composition of the intestinal microbiota.'" *Id.* But it is undisputed that all bacteria in the ten enumerated classes are **not** functionally equivalent. *See, e.g.,* Ex. B, ¶¶61, 69, 90; Ex. C, ¶¶34, 35, 40, 44, 90, 105-110; D.I. 260, Ex. 20 at 46:23-49:18. This lack of functional equivalence is enough to find the Markush group improper and therefore indefinite.

Recognizing this problem, Finch/UMN fall back on two rhetorical tricks. First, they advance a circular argument—that because the goal is to restore a subject's healthy gut biome, the Markush group can only include members of the bacterial classes that advance that goal. During claim construction and in responding to this motion, Finch/UMN have argued that the Markush group is just that—a Markush group that does not require active selection of particular bacteria. D.I. 91 at 53-59; D.I. 281 at 8-10. Finch/UMN's argument that the Markush group cannot include harmful bacterial strains because the bacteria come from a healthy human donor does not track the language of all of the asserted claims. *See* D. I. 281 at 8-9; D.I. 282, Ex. 65, ¶61; D.I. 260, Ex. 18, ¶¶69, 90; D.I. 260, Ex. 20 at 100:9-13. Although the '012 patent claim 1 references "a healthy human fecal donor[]," the "healthy" requirement is absent from '914 patent claim 9 and both the "healthy" and "human" requirements are absent from '914 patent claim 4. Further, it is entirely possible that even a healthy human fecal donor's microbiota includes some harmful bacteria. Ex. D, ¶72. And the microbiota of (not-necessarily healthy) humans, or of (healthy or non-healthy) non-humans, could contain strains of harmful bacteria from within the ten enumerated classes. *See* D.I. 260, Ex. 20 at 100-106.

Finally, Finch/UMN attempt to dismiss the simple mathematical logic that a claim to

"decreasing the relative abundance of one or more members of the phylum Proteobacteria" ('914 patent) could not be achieved by including all three members of the Markush group that are Proteobacteria. D.I. 260, Ex. 5 at cls. 4, 9. Similarly, "increasing the relative abundance of one or more members of the phylum Firmicutes" will not be achieved if none of the selected members of the Markush group are from the phylum Firmicutes. D.I. 260, Ex. 6 at cl. 1. This is not, as Finch/UMN suggest, bare attorney argument, but is straightforward logic, which the Court is free to credit. FED. R. EVID. 201; *see* 29 AM. JUR. 2D EVID. § 108; *see also* D.I. 258 at 9-10.

C. The asserted claims of the UMN patents lack written description support for the % change limitation and the Markush group

The asserted claims of the UMN patents are also invalid due to lack of written description support for both the Markush group and the relative abundance limitation. D.I. 258 at 10-13. The specification must clearly allow a POSA to recognize that the inventor invented what is claimed. *Allergan USA, Inc. v. MSN Lab'ys Pvt. Ltd.*, --- F. Supp. 3d ---, 2023 WL 6295496, *3 (D. Del. Sept. 27, 2023) (cleaned up); *Lipocine Inc. v. Clarus Therapeutics, Inc.*, 541 F. Supp. 3d 435, 444-45 (D. Del. 2021). This requires an objective inquiry into the four corners of the specification from the perspective of a POSA. *Allergan*, 2023 WL 6295496, *3 (cleaned up).

The asserted claims of the UMN patents are to a large number of compositions which allegedly effect certain changes in a patient's gut microbiome. Finch/UMN argues that the Markush group claims a genus of compositions that are structurally similar, and that the structural features of the group are set forth in the specification. D.I. 281 at 9-10. Not so. The various classes of bacteria and percent changes in Firmicutes and Proteobacteria are just part of laundry list recitations in the UMN patents' specification, without any elaboration as to their structural or functional characteristics, alone or in combination. *Lipocine*, 541 F. Supp. 3d at 462-64; D.I. 260, Ex. 5 at 5:19-29, 7:37-8:19, 15:21-52. The specification thus does not describe

the structural features of the members of the Markush group, much less any structural features common to them. And even if it did, Finch/UMN do not substantively address the % change limitations present in each of the asserted UMN claims—a **functional** limitation that also must find support in the specification. Nothing in the specification allows a POSA to determine which Markush group members meet that functional limitation. Especially given that no expert or inventor can even read the figures in Example 1—the **only** information supporting both the Markush group and the required microbiota percent changes—there is nothing in the specification that would reasonably convey to anyone that the inventor had possession of the functional requirements of the claims. *See generally, Lipocine*, 541 F. Supp. 3d 435; *see also Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); *Minemyer v. B-Roc Reps., Inc.*, 695 F.Supp.2d 797, 804-805 (N.D. Ill. 2017).

Ferring/Rebiotix maintain that *Allergan*, 2023 WL 6295496, is instructive, as set forth in Ferring/Rebiotix's opening brief. D.I. 258 at 13. Judge Bryson's opinion in *Lipocine* is also instructive. 541 F. Supp. 3d 432 (D. Del. 2021). At issue there were method of treatment claims that resulted in certain target testosterone serum concentrations using the claimed formulations. Judge Bryson noted that even those claims that included some limitation on the excipients used in the formulations were broad and covered "an expansive range of compositions." *Id.* at 449-50. The court found the claims invalid as lacking written description because the examples in the patents contained a "paucity of clinical testing" and did not make it clear which of the claimed formulations, if any, "can be used successfully in the claimed methods." *Id.* at 451-52. The same is true here. Thus, the asserted claims of the UMN patents are invalid for lack of written description.

D. Finch/UMN cannot show literal infringement of the particle size limitations and are barred from asserting the limitations are met under the DOE

1. Finch/UMN cannot prove direct infringement

The asserted claims of the UMN patents contain limitations regarding the size of the particles in the composition and require either that the composition contain "no particle having a size of greater than 0.5 mm," D.I. 260, Ex. 5 at cl. 9; D.I. 260, Ex. 6 at cl., or that the composition is "capable of passing through a 0.5 mm sieve" D.I. 260, Ex. 5 at cl. 4, ("the particle size limitations").

First, Finch/UMN argue that that "comprising" allows them to ignore the particle size limitations. D.I. 281 at 15-16. This is counter to controlling case law, which recognizes that "comprising" permits the addition of unrecited elements but cannot "remove the limitations that are present." *Power Mosfet Techs., L.L.C. v. Siemens AG*, 378 F.3d 1396, 1409 (Fed. Cir. 2004); *see also Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998). ("'Comprising' is not a weasel word with which to abrogate claim limitations.") Nor may "comprising" be used to avoid a relinquishment in claim coverage made during prosecution. *Spectrum,* 164 F.3d at 1379. Here, Finch/UMN added the particle size limitation to overcome patentability rejections. *See*, § II.D.2. They cannot now recapture that subject matter. Nor can they "remove the limitations" expressly included in the claims. *Power Mosfet*, 378 F.3d at 1409.

According to Finch/UMN the composition can have any amount of material that is larger than 0.5 mm or incapable of passing through a 0.5 mm sieve, provided at least some part of the composition is smaller. This interpretation effectively vitiates the particle size limitation, since any composition of fecal matter will have **some** particles that are smaller than 0.5mm and that can pass through a 0.5mm sieve. *See, e.g.*, *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1382-83 (Fed. Cir. 2000) (rejecting a patentee's attempt to contort the word "comprising" to extend the claim to a product containing more of a chemical than that recited in the claim). This court should reject Finch/UMN's "attempt to carve out a portion of" the composition "not recited

in the claim . . . because it would read out of [the '012 patent claim 1 and the '914 patent claims 4 and 9] the express claim" limitation that **no particle** may exceed the recited size limitation. *Id*.

Finch/UMN also offer no support "that REBYOTA—post-manufacturing—contains fecal extract capable of passing through a 0.5 mm sieve," and their reference to Ferring/Rebiotix's expert, Dr. Johnson, misstates the record. D.I. 281 at 15 (citing D.I. 283, Ex. 94 ¶211). Paragraph 211 of Dr. Johnson's report says [redacted] But Finch/UMN's "comprising" argument fails as to this "capable of" limitation for an additional reason. In claim 4 of the '914 patent, where this limitation is found, the limitation appears in a wherein clause that "comprising" does not modify.

Finch cannot overcome its failures by pointing to the stomacher bag. D.I. 281 at 16. That bag is not the accused product, and, unlike a metal sieve, is made of flexible material that allow particles larger than , which Dr. Johnson's testing demonstrated are present in the final REBYOTA product. The 0.5 mm limitation is a hard limit that, under the Court's construction, must be shown by sieving (not use of a stomacher). Using sieves, Dr. Johnson demonstrated that there are larger particles, and Finch/UMN's expert had to concede this undisputed evidence.

Nonetheless, Finch/UMN argue that Dr. Benson's reply expert report somehow rebutted Dr. Johnson's testing and analysis. D.I. 281 at 16 (citing D.I. 282, Ex. 96, ¶¶97-128). Not so. Criticism of Dr. Johnson's protocol cannot create a triable issue where Dr. Benson's own report acknowledges particles sizes of greater than . D.I. 282, Ex. 96, ¶¶102, 103, 128. Finch/UMN has not provided evidence establishing that all the particles of REBYOTA in fact can pass through a 0.5 mm sieve, as required by the claims. To merely speculate that if one were to change Dr. Johnson's protocol by washing the larger particles with an unspecified amount of additional saline, forcing apart clumps, or rotating individual particles Tetris-like to force them

through the sieve, there *might* be no remaining residue, is insufficient to create a genuine fact issue. Summary judgment of no literal infringement should issue.

2. Finch/UMN are barred from asserting DOE for the particle size limitations

Ferring/Rebiotix has provided three independent reasons that the DOE arguments advanced by Finch/UMN's expert Dr. Benson fail as a matter of law: (1) prosecution history estoppel, (2) an improper focus on the claim as a whole in determining equivalence, and (3) vitiation of the particle size limitations. Any one of these three reasons is enough to bar DOE.

a. PHE bars DOE for the particle size limitation

Finch/UMN concede, as they must, that they added the particle size limitations after examiner rejections. These amendments create a presumption that they cannot overcome.

Finch/UMN are barred from contending that the "capable of passing through a 0.5 mm sieve" limitation of the '914 patent is infringed under the DOE because the applicants added this limitation as part of an independent claim after it was initially part of a dependent claim from an independent claim that was rejected. D.I. 258 at 18. Finch/UMN's argument that PHE does not apply because the dependent claim containing the particle size limitation was only withdrawn in response to an election requirement misses the point. The point is that the limitation was added by amendment in a new independent claim to gain allowance. *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1305-06 (Fed. Cir. 2005).

Finch/UMN's theory for why *Biagro* does not apply relies on the argument that the rewritten dependent claim was an "entirely new claim[] of wholly different scope" such that the "[c]ancelled claims were not replaced with dependent claims written in independent form." D.I. 281 at 17-18. That is not true. Both the canceled dependent claim and the claim introduced by amendment include the limitation "capable of passing through a 0.5 mm sieve." The new claim

was not "drawn to completely different subject matter than the claims as originally filed." *Id.*

In order to overcome the *Festo* presumption that attaches from the applicant's amendments adding the particle size limitations in response to rejections, Finch/UMN is left to argue that the *Festo* tangential exception applies, but that argument fails, as it is clear that the applicant viewed the particle size limitation as relevant to patentability. Applicant made clear during the prosecution of U.S. Patent No. 9,968,638 ("the '638 patent")—the parent application to the '914 and '012 patents—that this was the reason for adding the particle size requirement in the first place. D.I. 258 at 17-19; *see* D.I. 263, Ex. 37 at PDF 84-85 (arguing that the prior art does not "provide for particles of non-living material, **let alone no particles of non-living material having a size of greater than 0.5 mm**.") (emphasis added).

Indeed, Finch/UMN concede that applicant added "the particle size element" at the examiner's urging in order to overcome the prior art. D.I. 281 at 18-19. That the examiner required the applicants to **also** add additional limitations does not mean that the size limitations were not material. Thus, Finch/UMN's argument that the tangential relation exception applies cannot overcome the presumption that PHE applies.

b. Dr. Benson's DOE argument is improper

Finch/UMN continues to improperly focus its DOE analysis on "the totality of the particles in the context of the claimed composition." D.I. 281 at 21. This runs contrary to long-established precedent that "proof of equivalents must be limitation specific, not focused only on the claim as a whole," though the inquiry may be informed by the context of the role played by each element in the claim. *VLSI Tech. LLC v. Intel Corp.*, 87 F.4th 1332, 1342 (Fed. Cir. 2023) (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997)). Dr. Benson's analysis goes beyond using the context of the claim to inform his inquiry and crosses over into impermissible consideration of the claim as a whole, or, pivoting away from the claim

entirely, the function of REBYOTA. The passages from Dr. Benson's reports cited by Finch/UMN make this clear. Dr. Benson states, "**REBYOTA** would nonetheless perform the same function in the same way to achieve the same clinical outcome" and " …would result in substantially the same bacterial composition …" D.I. 283, Ex. 78 ¶362 (emphasis added); *see also* D.I. 283, Ex. 96 ¶¶149, 152. Dr. Benson's analysis is improper as a matter of law.

c. Dr. Benson's DOE argument vitiates the particle size limitation

Dr. Benson effectively contends that as long as some particles are smaller than 0.5 mm, it is fine if there are a substantial number larger than the claimed size limit as well. Finch/UMN's response to Ferring/Rebiotix's motion on this point is to assert that "no particle" in the claim is not a "militant absolute." D.I. 281 at 20. But to say that an 0.5 mm maximum particle size is really the same thing as having some particles smaller than 0.5 mm and some larger than 0.5 mm (perhaps considerably larger) would vitiate that requirement. *See Warner-Jenkinson*, 520 U.S. at 29 ("[T]he application of the doctrine [of equivalents], even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety."); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1344–45 (Fed. Cir. 2016) (rejecting a theory of infringement under the doctrine of equivalents that would vitiate a claim limitation by rendering it meaningless).

E. The asserted claims of the UMN patents are invalid because the "extract" terms lack written description support

Responding to Ferring/Rebiotix's motion for summary judgment that the "extract" term in the asserted claims of the UMN patents lacks written description support, Finch/UMN argues first that the issue was not raised in Ferring/Rebiotix's expert reports. This is incorrect. The issue was addressed by Drs. Savidge and Johnson in their reports. Ex. D at ¶¶48-54, 169, 298; D.I. 263, Ex. 26 at ¶¶71, 240-45. Further, the deposition of Finch's expert on the UMN patents and §

112, Dr. Schloss, made clear that his opinion was predicated on reading limitations from the examples into the claims. *See, e.g.*, D.I. 260, Ex. 20 at 190:5-191:20. Specifically, Dr. Schloss opined that the claims must be read in light of the Examples to understand the scope of what is claimed. Ex. E at 102:22-24, 182:5-17, 212:11-13. The examples only disclose methods of manufacture through filtering and washing. D.I. 260, Ex. 5 at 19:37-29:3. There is no written description support for the scope of "extract" as more broadly construed.

When the specification describes a narrow set of embodiments, the claim cannot be applied more broadly if there is an absence of written description support for the broader application of the claim. *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002) ("[A] broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope."); *see also Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479-80 (Fed. Cir. 1998). Here, there is not written description support for all "chemical and physical process[es]" that may be used to obtain a substance from a material, mixture, organism, or part of an organism. *See* D.I. 91 at 61.

In view of this narrow disclosure in the specification, Finch/UMN argue that the term "extract" is a term of art, such that general knowledge can supply written description. D.I. 281 at 13. But *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1367-68 (Fed. Cir. 2006), cited by Finch/UMN, does not stand for such a broad proposition. Rather, *Falko-Gunter* permitted "accessible literature sources" to provide some of the written description support. *Id.* at 1368. Finch/UMN has not provided such "accessible literature sources." *See also FWP IP ApS v. Biogen MA, Inc.*, 749 F. Appx. 969, 973 (Fed. Cir. 2018) ("case law requires the specification itself to provide the blaze marks necessary to guide a skilled artisan to the claimed invention").

F. Summary judgment of noninfringement of the asserted claims of the '702, '309, and '193 patents is appropriate because REBYOTA's FDA-approved use is not "treatment"

REBYOTA is FDA-approved for the "prevention of recurrence of *Clostridioides difficile* infection." It is "**not** indicated for **treatment** of CDI." D.I. 263, Ex. 39 at FER_RBX02700270-271. REBYOTA received FDA approval on November 30, 2022. Ex. F at FINCH_UMN_0017067. All asserted claims of the '702, '309, and '193 patents claim some aspect of "treating" CDI. There is no evidence that REBYOTA has been prescribed for off-label uses following FDA approval. Nor is there evidence of any allegedly infringing uses prior to FDA approval. Finch/UMN do not dispute these basic facts. Instead, Finch/UMN catalog instances where variations of "treat" were used in connection with REBYOTA, and also Ferring/Rebiotix's statements during FDA approval process. But all of the statements Finch/UMN rely on were made **before** FDA approval. *See* D.I. 282, Ex. 105 (9/2/2022); D.I. 282, Ex. 106 (10/20/2014); D.I. 282, Ex. 107, ¶85 (citing three papers, two from 2022 and one from 2023); D.I. 282, Ex. 108 (11/12/2015); D.I. 282, Ex. 109 (10/26/2022).

Responding to Ferring/Rebiotix's evidence of the ACG Guidelines' distinction between "treatment" and "prevention of recurrence," Finch/UMN's sole response is to pull a quotation not from the ACG Guidelines themselves, but from Dr. Stollman's Reply Report. D.I. 281 at 26 (citing D.I. 282, Ex. 112). However, the isolated quotation is taken out of context, and is in a section concerning immunocompromised patients—following a "Key concept" recommendation that vancomycin or fidaxomine be used as the first line for treatment of immunocompromised patients. D.I. 263, Ex. 42 at FER_RBX00239412. Finch/UMN's citations to expert deposition testimony is similarly taken out of context and misleading. For example, the quotations from Dr. Kraft's deposition are taken from separate question/answer pairs and are not fairly read to have the meaning Finch/UMN suggests by stitching them together. D.I. 281 at 25-26 (citing D.I. 282,

Ex. 104). Similarly, Dr. Polage's testimony relates to trials that pre-date FDA approval. *Id.* (citing D.I. 282, Ex. 110). And Finch/UMN's sole response to the file history's disclosure that Borody could not get a claim to "prevention" is a conclusory dismissal as "irrelevant." D.I. 281 at 26. That is not enough to gin up a dispute sufficient to defeat summary judgment.

Even if Ferring/Rebiotix [redacted] and [redacted], REBYOTA is not approved for "treating" CDI. Consequently, all of Finch/UMN's cited evidence is irrelevant, and the Court should enter summary judgment of noninfringement of all asserted claims of the '702, '309, and '193 patents.

G. The term "substantially entire microbiota" is indefinite

Finch/UMN assail Ferring/Rebiotix's argument that "substantially entire microbiota" (the "SEM term") in claim 11 of the '702 patent is indefinite as an effort to reargue claim construction. D.I. 281 at 21-23. But, during claim construction, the Court specifically reserved Ferring/Rebiotix's right to raise indefiniteness later. D.I. 148 at 110:20-21. Finch/UMN contend that the SEM term is a permissible "term of degree." D.I. 281 at 22. They then argue that intrinsic and extrinsic evidence may be consulted in determining whether terms of degree are sufficiently definite. *Id.* But here, it is precisely that intrinsic and extrinsic evidence that dooms the SEM term. For the intrinsic evidence, Finch/UMN now rely on precisely the "explicit numerical guidance" that formed the basis of Ferring/Rebiotix's proposed claim construction. *Compare id.* at 22 *with* D.I. 91 at 42-44. But during claim construction Finch/UMN argued against limiting the SEM term to that numeric guidance. D.I. 91 at 40-41, 44-46. And Finch/UMN now acknowledges that the numeric guidance in the specification was the basis for the Examiner to find the term definite. D.I. 281 at 22-23; *see* D.I. 258 at 28 (citing prosecution history). Moreover, even that guidance is essentially limitless, providing, in part, "having *no more than* [0.1%-1.0%] *or more* non-fecal floral material." D.I. 260, Ex. 1 at 7:63-8:2 (emphasis

added). Similarly, Finch/UMN's expert testified that compositions with just 10% of the original microbiota could be SEM "if their intent was the same and they did a lousy job." D.I. 263, Ex. 47 at 132:21-133:12. By this logic, any amount of the microbiota could constitute SEM, which fails to "provide objective boundaries for those of skill in the art." *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014).

Finch/UMN rely heavily on *Guangdong Alison Hi-Tech Co. v. International Trade Commission*, which found that "lofty batting" was not indefinite, in view of the specification. 936 F.3d at 1359-1361. In *Guangdong*, the specification was "replete with examples and metrics," including specific products and metrics for the "fineness of fibers," "the cross-sectional area of the fibers," "the thermal conductivity of the batting," "the compressibility and resilience of the batting," and "the density of the batting." *Id.* at 1361. The '702 Patent provides no comparable details—particularly since the numeric passage was determined not to be definitional. Recognizing this deficiency, Finch/UMN argue that the "objective way" to measure SEM is that "as much of the microbiome as possible" is preserved. D.I. 281 at 23. But this standard provides no objective guidance and is no more a "question of fact" than "unobtrusive manner" in *Interval Licensing*, 766 F.3d at 1371-1373. *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1259-61 (Fed. Cir. 2014) also does not support Finch/UMN. In *DDR*, the court determined that the term "look and feel" as applied to computer interfaces is a well-understood term of art with an established meaning, contrasted with "facially subjective" terms like "unobtrusive manner" or "aesthetically pleasing." *Id.* The SEM term, as construed, is indefinite.

H. The Borody patents are unpatentable under 35 U.S.C. § 101

All asserted claims of the Borody patents are directed to a natural product—a human fecal microbiome preparation—and are unpatentable under Section 101. In response, Finch/UMN argue that Dr. Borody's inventions include "processing steps" and "specific,

unconventional ingredients that gave the formulations 'prolonged life,'" particularly the addition of a cryoprotectant and an antioxidant, ostensibly "to preserve viability for transport to a remote facility." D.I. 281 at 27-28. The chief deficiency in Finch/UMN's argument is that the asserted claims do not specify a threshold amount of either cryoprotectants or antioxidants, nor do they require that either transform the nature of the fecal flora or its ability to restore the microbiome. Fecal compositions containing even *de minimis* amounts of cryoprotectants and/or antioxidants fall within the scope of the asserted claims, and this is fatal to the patentability of those claims.

Finch states that "[a]ll experts agree that" cryoprotectants and antioxidants can perform certain functions to protect fecal flora. D.I. 281 at 29. This, however, misses the real issue, which is whether the claims cover any embodiment that does not have "markedly different characteristics" from a naturally occurring composition. None of the asserted claims require a specific amount of either a cryoprotectant or an antioxidant, and Finch/UMN have not suggested that the claims should be construed so as to require a specific amount. Instead, Finch/UMN's only response is that a POSA would not add only a *de minimis* amount of those ingredients. D.I. 281 at 32. But that does not change the literal scope of the claims.

Without an effective amount threshold in the claims, compositions within the scope of the claims (e.g., those with negligible amounts of cryoprotectant and/or antioxidant) do not have "markedly different characteristics" from naturally occurring fecal flora. Finch/UMN admit that "it is 'undisputed' that cryoprotectants and antioxidants are unnecessary for preserving clinical efficacy." *Id.* at 32. And, as the "Frozen vs Fresh" article demonstrates, stool can be mixed with nothing more than bottled water, frozen, and stored for a period of time before use without impacting clinical performance. D.I. 264, Ex. 51 at FER_RBX03012341-43. Therefore, the literal scope of the claims encompasses compositions wherein the added cryoprotectant and/or

antioxidant is present in negligible amounts that do not transform the characteristics of the naturally occurring fecal flora and its ability to restore the microbiome.

ChromaDex, Inc. v. Elysium Health, Inc., 59 F.4th 1280 (Fed. Cir. 2023) is directly on point. Just as the composition containing the isolated milk protein in *ChromaDex* lacked markedly different characteristics from naturally occurring milk, the composition claimed in the Borody patents lacks markedly different characteristics from un-augmented fecal extract (including a pharmaceutically effective amount of fecal flora after freezing and transportation). A recent decision from this District is closely analogous. In *Regenexbio Inc. v. Sarepta Therapeutics, Inc.*, No. 20-1226-RGA, 2024 WL 68278 (D. Del. Jan. 5, 2024), a claim directed to a "cultured host cell" was held unpatentable because the inventors "have not changed any of the claimed invention's naturally occurring components," and therefore, the claim did not satisfy the "markedly different characteristics" standard. *Id.* at **5-6 (also indicating this finding would be sufficient to render the claims unpatentable without separately considering the *Alice/Mayo* framework). The *Regenexbio* court also found that "Plaintiffs' contention that the [asserted claims] have utility for gene therapy is unpersuasive" because "Plaintiffs do not point to anything in the claims or specification that requires utility for gene therapy." *Id.* In the same way, it is irrelevant that cryoprotectants and/or antioxidants may improve the function of the claimed compositions if present in sufficient quantities because the Borody claims encompass compositions having *de minimis* amounts of both. And when "claims cover both eligible and ineligible subject matter [they] are not patentable." *Id.* at *6.

The addition of standard enema packaging likewise does not alter the analysis under *Alice* step one or step two. D.I. 281 at 28, 30. Under *Alice* step one, the claim is directed to the fecal extract, not to the standard enema packaging. Under step two, this standard packaging does

not add an inventive concept. The asserted claims of the Borody patents fail under *Alice* step one and step two and are unpatentable under Section 101.

I. Mr. Malackowski's testimony should be excluded

1. Mr. Malackowski's [redacted] upfront access fee is not supported or reliable

Section 284 makes it clear that a "reasonable royalty [is] for the **use made** of the invention by the infringer." 35 U.S.C. § 284 (emphasis added). Finch/UMN do not dispute that it is improper to consider what the parties may have agreed to as part of a real-world agreement beyond **use** of the patents-in-suit in the hypothetical negotiation analysis. Finch/UMN also do not dispute that the [redacted] proposed by Mr. Malackowski would be paid even if there is no use made of the invention. D.I. 260, Ex. 8 at 39:10-40:8; 42:10-43:2. Finch/UMN argue that the license would be giving Ferring/Rebiotix the **ability to use** the invention, but that is neither consistent with the damages statute nor with Federal Circuit precedent. *Aqua Shield v. Inter Pool Cover Team*, 774 F.3d 766, 770 (Fed. Cir. 2014). Finch/UMN's cited authority is inapplicable. In *Transocean v. Maersk*, 699 F.3d 1340, 1357-58 (Fed. Cir. 2012), the jury awarded a lump sum fee as damages for an infringing offer for sale and sale. The defendant protested that it would not have paid so much absent use of the invention beyond the sale, but that was a fact question for the jury. *Id.* at 1357–59. Here, in contrast, Mr. Malackowski testified that the [redacted] would be paid absent any infringement at all. Ex. G at 49:13-53:12. Mr. Malackowksi's only support for that upfront fee is agreements for the sale of products, not naked patent licenses. D.I. 264, Ex.55 at FINCH_UMN_0019900. In the merger, Ferring bought Rebiotix's product developed using Rebiotix's IP. D.I. 264, Ex. 54 at FER_RBX02738157, -182, -242, -259, -442.

Finch/UMN's arguments regarding license comparability are also unavailing. Finch/UMN argue that Dr. Benson's single statement that the Nestle agreement involves FMT

treatment satisfies the comparability requirement. D.I. 281 at 36. Not so. Mr. Malackowski performed no economic comparability whatsoever. The value that a patent contributes to a product can vary dramatically depending on the patent's scope. To show comparability, an expert must compare the scope of the licensed rights. Here, Mr. Malackowski does not know the scope of the rights that were licensed in the Nestle agreement and thus cannot answer that question. As to the merger agreement, Finch/UMN do not dispute that Ferring purchased far more than REBYOTA in the Ferring/Rebiotix merger. Finch/UMN also do not dispute that Mr. Malackowski did not apportion the amount paid in the merger to REBYOTA as compared to the other assets involved. These failures are fatal to his reliance on these agreements.

Finally, Mr. Malackowski justifies the magnitude of his upfront payment based in part on the premise that Ferring would acquire exclusive rights. Yet Finch/UMN concede that they retained and would retain the rights to license the patents-in-suit and to practice the patents post-trial. D.I. 260, Ex. G at 24:10-25:7. What Ferring would have received, and what must be valued, is a non-exclusive license.

2. Mr. Malackowski's [redacted] royalty rate lacks reliable support

UMN/Finch fail to explain how Mr. Malackowski's [redacted] royalty rate is tethered to any comparable license agreement or reliable calculation. The Nestle/Seres agreement had no royalty rate, but rather a 50/50 profit split. The Rebiotix agreement had a [redacted] royalty rate (much lower than [redacted]) and was for the sale of an entire company. Mr. Malackowski's royalty also lacks support because, as he admits, he does not know the value of the novel elements of the patents-in-suit to REBYOTA. Ex. G at 167:4-168:3; 175:10-24. Therefore, he cannot have done any economic apportionment based on "the incremental value that the patented invention adds to the end product" when arriving at his 30% royalty rate. *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014).

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